DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

409

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-84

September 16, 1997

Mr. Jerry Jones
Chief Executive Officer
Apria Healthcare, Inc.
3500 Hyland Avenue
Costa Mesa, California 92626

Dear Mr. Jones:

Inspection of your medical gas filling operation located at 5414 Beaumont Center Road, Tampa, Florida 33634, on August 21-22, 1997, by FDA Investigator Christine M. Humphrey, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Good Manufacturing Practice Regulations [Title 21, Code of Federal Regulations (CFR), Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the manufacturing, testing, and release for distribution of liquid medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed that there is no assurance that your medical liquid oxygen products meet applicable standards of identity, strength, quality, and purity in that bulk medical liquid oxygen is not adequately tested to determine conformance with appropriate specifications before vehicle mounted cryogenic vessels are filled. Review of at least seven (7) bulk lots found that the performance of identity and strength testing of incoming bulk medical liquid oxygen is inconsistent. Our investigator documented seven (7) bulk lots of medical liquid oxygen in which there was no documentation of identity or strength testing or, in lieu of testing, the receipt of a valid Certificate of Analysis (COA) from the supplier and the performance of an identity test.

Batch production and control records identifying each step in the manufacturing process of medical liquid oxygen are incomplete in some instances in that pre-fill checks for each home cryogenic unit filled and for each lot of bulk oxygen received were not documented. The investigator found at least five (5) bulk lots which did not possess documentation of pre-fill checks performed prior to the filling of your vehicle mounted vessel. In addition, Apria Route Sheet/Manifests dated March 25, 1997, July 21, 1997,

and July 25, 1997, and accompanying work orders reveal that although more than one home cryogenic unit is filled at a patient's home, individual pre-fill checks for each unit filled are not documented.

The investigator also observed instances of failure to follow written policies and procedures. For example, Apria Policy #604-055 requires that Work Order/Service documents must be filled out completely to ensure traceability of medical liquid oxygen transfilled and delivered to the home. However, review of at least six (6) work orders show that these documents are not always completed with both a serial number and lot number as required by the written procedure. Also, Apria Policy #604-060 states that Route Sheet/Manifest records shall be used to document delivery of high pressure cylinders to include the cylinder lot numbers. For example, Route Sheet/Manifests dated March 26, 1997, July 24, 1997, and July 25, 1997, do not document the serial numbers of any or all cylinders distributed.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the GMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Martin E. Katz, Compliance Officer, U. S. Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 262.

Sincerely,

Douglas D. Tolen
Director
Florida District